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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,404	03/16/2006	Ryuichi Higuchi	TOYA108.013APC	8010

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EXAMINER

BLAND, LAYLA D

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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07/21/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/572,404	HIGUCHI ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is a response to Applicant's amendment submitted April 30, 2009, wherein claim 18 is amended and claim 23 is canceled. Claim 18 is pending and is examined on the merits herein.

Applicant's declaration of Miyuki Tanaka submitted April 30, 2009 under 37 CFR 1.132, is acknowledged and will be further discussed below.

In view of the cancellation of claim 23, all rejections made with respect to that claim in the previous office action are withdrawn.

In view of Applicant's amendment submitted April 30, 2009, the rejection of claim 18 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Abou Zeid is withdrawn. Abou Zeid does not teach 9,19-cyclolanostan-3-ol.

The terminal disclaimer filed on April 30, 2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on U.S. Application No. 11/577,301 has been reviewed and is accepted. The terminal disclaimer has been recorded. The rejection of claim 18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 11/577,301 is withdrawn.

The following rejection is maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Ajabnoor (Journal of Ethnopharmacology, 28 (1990) 215-220, PTO-1449 submitted May 22, 2006), as evidenced by Tanaka et al. (Biol. Pharm. Bull. 29(7) 1418-1422 (2006), of record).

Ajabnoor teaches administration of an extract of *Aloe barbadensis* leaves and its bitter principle to alloxan-diabetic mice, resulting in a hypoglycemic effect [see abstract]. The extract was obtained by exhaustive liquid-liquid extraction with ethyl acetate and further purification by back extraction with saline and again with ethyl acetate [page 216, plant material]. The subjects were mice with induced hyperglycemia [page 216, Animals]. The mice were treated with up to 500mg/kg twice a day of aloe extract or 5 mg/kg of the bitter principle, resulting in decreased FPG [page 217, Results and Discussion].

Tanaka et al. teach that the following compounds [page 1420, Figure 4] were isolated from Aloe vera gel [see abstract]:

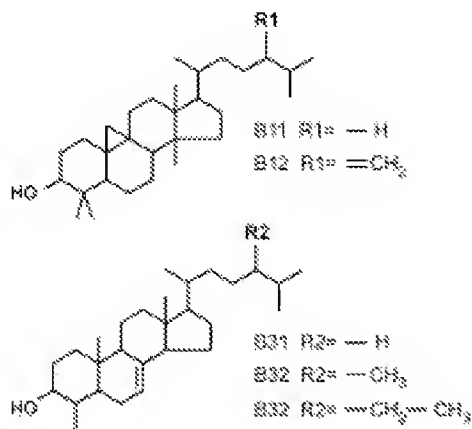


Fig. 4. Chemical Structures of Compounds B11, B12, B31, B32, and B33

Compound B11 is 9,19-cyclolanostan-3-ol. This compound is inherently present in *Aloe vera* gel.

Ajabnoor does not teach the concentration or amount of 9,19-cyclolanostan-3-ol administered to the mice. However, it is expected that Ajabnoor's extract meets the claim limitations because Ajabnoor's extract was obtained in much the same way as is described in the instant specification: extraction of the plant material using a polar organic solvent. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Response to Arguments

Applicant argues that Ajabnoor's extract does not contain 9,19-cyclolanostan-3-ol, and presents the declaration of Miyuki Tanaka in support. The Tanaka declaration of April 30, 2009 states that "a drained liquid from the cut leaves of aloe," extracted with ethyl acetate, contains no detectable amount of 9,19-cyclolanostan-3-ol. This result is unclear because the Tanaka declaration of May 15, 2008, stated that aloe vera juice contains 222.8 ng of 9,19-cyclolanostan-3-ol per gram. It is unclear why "aloe vera juice" would contain 9,19-cyclolanostan-3-ol while "drained liquid from the cut leaves of aloe" does not, because it is considered that these are substantially the same. An extract of aloe vera, such as the ethyl acetate extract taught by Ajabnoor, would be expected to contain an even higher concentration of 9,19-cyclolanostan-3-ol based on dry mass than would aloe vera juice itself, because impurities are removed during the extraction process (thereby increasing the amount of desired compound with respect to the total). Thus, it is unclear if the declaration of April 30, 2009 included measurement of the aloe vera extract as a whole, or only the bitter principle. It is noted that Ajabnoor teaches administration of aloes as well as administration of the bitter principle. Because the data in the Tanaka declaration is not clear, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **LAYLA BLAND** whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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/Layla Bland/
Examiner, Art Unit 1623

/Leigh C. Maier/
Primary Examiner, Art Unit 1623